

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 9, 1996.

Douglas J. Godesky.

Reports Clearance Officer.

[FR Doc. 96-31702 Filed 12-12-96; 8:45 am]

BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 96M-0461]

Allergan Optical; Premarket Approval of Refresh® CL Lubricating and Rewetting Drops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Optical, Irvine, CA, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of Refresh® CL Lubricating and Rewetting Drops. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 25, 1996, of the approval of the application.

DATES: Petitions for administrative review by January 13, 1997.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1744.

SUPPLEMENTARY INFORMATION: On May 6, 1996, Allergan Optical, Irvine, CA 92713-9534, submitted to CDRH an application for premarket approval of Refresh® CL Lubricating and Rewetting Drops. The device is a solution indicated for the lubrication and rewetting of soft contact lenses. The device helps to relieve dryness, discomfort, and irritation that may be associated with lens wear.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Ophthalmic Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On September 25, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360(g), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 13, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this

document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96-31744 Filed 12-12-96; 8:45 am]

BILLING CODE 4160-01-F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of its clinical hold review committee, which reviews the clinical hold orders that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held on February 11, 1997. Biological product companies may submit review requests for the February meeting by January 9, 1997.

ADDRESSES: Submit clinical hold review requests to Amanda Bryce Norton, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF-7), Food and Drug Administration, 5600 Fishers Lane, rm. 14-105, Rockville, MD 20857, 301-827-3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM-2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. If FDA